

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION: Ralph H. SCHWALL et al.

GROUP ART UNIT:

SERIAL NUMBER: NEW CONTINUATION APPLICATION

EXAMINER:

FILED: HEREWITH

FOR: HEPATOCYTE GROWTH FACTOR RECEPTOR ANTAGONISTS AND USES THEREOF

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. 1.97

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Applicant(s) wish(es) to disclose the following information.

REFERENCES

- Applicant(s) wish(es) to make of record the documents listed on the attached Form PTO-1449. Copies of the listed documents are attached, where required, as are either statements of relevancy or any readily available full or partial English translations of any non-English-language documents.

RELATED CASES

- Attached is a list of Applicant's(s') pending applications and issued patents which may be related to the present application. Copies of the documents, where required, are attached along with Form PTO-1449.

CERTIFICATION

The undersigned certifies that

- ☐ each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign or international patent office in a counterpart foreign or international application for the first time (to the knowledge of the undersigned, having made reasonable inquiry) not more than three months prior to the filing of this statement.
- ☐ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign or international patent office in a counterpart foreign or international application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement.

BASIS FOR CONSIDERATION

This Information Disclosure Statement is filed:

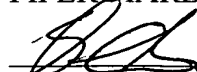
- without fee and within three months of the filing date of the application.
- ☐ without fee and within three months of the date of entry of the U.S. national stage.
- ☐ without fee and before the mailing date of a first Office Action on the merits (to the knowledge of the undersigned).
- ☐ without fee and with the appropriate certification above.
- ☐ without fee and with a new CPA application.
- ☐ without fee and with a Request for Continued Examination.
- ☐ with fee and before the mailing date of any of a Final Office Action, Notice of Allowance or an action that otherwise closes prosecution (to the knowledge of the undersigned).
- ☐ with fee, appropriate certification above, and before payment of the Issue Fee.

DEPOSIT ACCOUNT

- Please charge any additional fees for the papers being filed herewith and for which no check is enclosed herewith, or credit any overpayment to Deposit Account No. 50-1442.

Respectfully submitted,

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Form PTO 1449 (Modified)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO.	SERIAL NO.
		9491-057-27 CONT	NEW CONTINUATION APPLICATION
		APPLICANT RALPH H. SCHWALL, ET AL.	
LIST OF REFERENCES CITED BY APPLICANT (Use Several Sheets if Necessary)		FILING DATE HEREWITH	GROUP

1-c872 U.S. PTO  
09/995693  
11/29/01

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	AA	4,342,566	8/3/82	Theofilopoulos et al.			
	AB	4,816,567	3/28/89	Cabilly et al.			
	AC	5,227,158	7/13/93	Jardieu			
	AD	5,316,921	5/31/94	Godowski et al.			
	AE	5,328,837	7/12/94	Godowski et al.			
	AF	5,362,716	11/8/94	Kmiecik et al.			
	AG	5,547,856	8/20/96	Godowski et al.			

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION YES NO	
	AH	0 567 585 B1	11/3/93	EP		
	AI	WO 92/05184	4/2/92	PCT		
	AJ	WO 92/13097	8/6/92	PCT		
	AK	WO 92/20792	11/26/92	PCT		
	AL	WO 93/15754	8/19/93	PCT		
	AM	WO 93/23541	11/25/93	PCT		
	AN	WO 93/23550	11/25/93	PCT		
	AO	WO 94/04679	3/3/94	PCT		
	AP	WO 94/06909	3/31/94	PCT		
	AQ	WO 94/29348	12/22/94	PCT		
	AR	WO 95/01376	1/12/95	PCT		

## OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	AS	<u>Handbook of Monoclonal Antibodies</u> , Ferrone et al. Eds., Park Ridge, NJ: Noyes Publications, pps. 302-359 and Chapter 22 (1985)
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EXAMINER

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	AT	Asami et al., "Purification and Characterization of Hepatocyte Growth Factor from Injured Liver of Carbon Tetrachloride-Treated Rats" <u>J. Biochem.</u> 109:8-13 (1991)	
	AU	Bellusci et al., "Creation of an Hepatocyte Growth Factor/Scatter Factor Autocrine Loop in Carcinoma Cells Induces Invasive Properties Associated with Increased Tumorigenicity" <u>Oncogene</u> 9:1091-1099 (1994)	
	AV	Boerner et al., "Production of Antigen-Specific Human Monoclonal Antibodies From In Vitro-Primed Human Splenocytes" <u>The Journal of Immunology</u> 147 (1): 86-95 (1991)	
	AW	Bottaro et al., "Identification of the Hepatocyte Growth Factor Receptor as the c-met Proto-Oncogene Product" <u>Science</u> 251:802-804 (February 15, 1991)	
	AX	Brodeur et al., "Mouse-Human Myeloma Partners for the Production of Heterohybridomas" <u>Monoclonal Antibody Production Techniques and Applications</u> , New York: Marcel Dekker, Inc. Pps. 51-63 (1987)	
	AY	Bruggemann et al., "Designer Mice: The Production of Human Antibody Repertoires in Transgenic Animals" <u>Year in Immunology</u> 7:33-40 (1993)	
	AZ	Carter et al., "Humanization of an anti-p185 <sup>HER2</sup> antibody for human cancer therapy" <u>Proc. Natl. Acad. Sci.</u> 89:4285-4289 (1992)	
	BA	Chamow et al., "A Humanized, Bispecific Immunoadhesin-Antibody That Retargets CD3+ Effectors to Kill HIV-1 Infected Cells" <u>Journal of Immunology</u> 153:4268-4280 (1994)	
	BB	Chan et al., "Identification of a Competitive HGF Antagonist Encoded by an Alternative Transcript" <u>Science</u> 254:1382-1385 (1991)	
	BC	Chan et al., "Isoforms of Human HGF and Their Biological Activities" <u>Hepatocyte Growth Factor-Scatter Factor (HGF-SF) and the C-Met Receptor</u> , I.D. Goldberg and E. M. Rosen eds., Basel:Birkhauser Verlag pps. 67-79 (1993)	
	BD	Chothia, "Domain Association in Immunoglobulin Molecules: The Packing of Variable Domains" <u>J. Mol. Biol.</u> 186:651-663 (1985)	
	BE	Chothia and Lesk, "Canonical Structures for the hypervariable regions of immunoglobulins" <u>J. Mol. Biol.</u> 196(4):901-917 (1987)	
	BF	Cole et al., "The EBV-Hybridoma Technique and Its Application to Human Lung Cancer" <u>Monoclonal Antibodies and Cancer Therapy</u> , Reisfeld et al., New York:Alan R. Liss, Inc. pps. 77-96 (1985)	
	BG	Comoglio, "The HGF Receptor and Its Ligand: Structure, Signal Transduction and Biology" <u>Cell Biology International</u> (abstract only) 18(5):375 (1994)	
	BH	Comoglio, "Structure, Biosynthesis and Biochemical Properties of the HGF Receptor in Normal and Malignant Cells" <u>Hepatocyte Growth Factor-Scatter Factor (HGF-SF) and the C-Met Receptor</u> , I.D. Goldberg and E.M. Rosen eds., Basel:Birkhauser Verlag pps. 131-165 (1993)	
	BI	Comoglio et al., "The Met/HGF-SF Receptor" <u>Positive Growth Control</u> (Abstract Only) 192:H215	
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	BJ	Cooper et al., "Amplification and Overexpression of the MET Gene in Spontaneously Transformed NIH3T3 Mouse Fibroblasts" <u>EMBO Journal</u> 5(10):2623:2628 (1986)					
	BK	Crepaldi et al., "Targeting of the SF/HGF Receptor to the Basolateral Domain of Polarized Epithelial Cells" <u>The Journal of Cell Biology</u> 125(2):313-320 (1994)					
	BL	David et al., "Protein Iodination with Solid State Lactoperoxidase" <u>Biochemistry</u> 13(5):1014-1021 (1974)					
	BM	de Sauvage et al., "Stimulation of Megakaryocytopoiesis and Thrombopoiesis by the c-Mpl Ligand" <u>Nature</u> 369:533-538 (June 16, 1994)					
	BN	Defrances et al., "The Presence of Hepatocyte Growth Factor in the Developing Rat" <u>Development</u> 116:387-395 (1992)					
	BO	Di Renzo et al., "Overexpression of the c-Met/HGF Receptor Gene in Human Thyroid Carcinomas" <u>Oncogene</u> 7:2549-2553 (1992)					
	BP	Di Renzo et al., "Selective Expression of the Met/HGF Receptor in Human Central Nervous System Microglia" <u>Oncogene</u> 8:219-222 (1993)					
	BQ	Fan et al., "Blockade of Epidermal Growth Factor Receptor Function by Bivalent and Monovalent Fragments of 225 Anti-Epidermal Growth Factor Receptor Monoclonal Antibodies" <u>Cancer Research</u> 53:4322-4328 (1993)					
	BR	Giordano et al., "Transfer of Motogenic and Invasive Response to Scatter Factor/Hepatocyte Growth Factor by Transfection of Human met Protooncogene" <u>Proc. Natl. Acad. Sci. USA</u> 90:649-653 (January 1993)					
	BS	Giordano et al., "Tyrosine Kinase Receptor Indistinguishable from the C-Met Protein" <u>Nature</u> 339:155-156 (May 11, 1989)					
	BT	Goding, "Production of Monoclonal Antibodies" <u>Monoclonal Antibodies: Principles and Practice</u> , Academic Press, pps. 59-103 (1986)					
	BU	Gohda et al., "Purification and Partial Characterization of Hepatocyte Growth Factor from Plasma of a Patient with Fulminant Hepatic Failure" <u>J. Clin. Invest.</u> 81:414-419 (1988)					
	BV	Gorman, C. "High Efficiency Gene Transfer Into Mammalian Cells" <u>DNA Cloning: A Practical Approach</u> , Glover, D.M., ed, Washington D.C.: IRL Press Vol. 2:143-190 (1985)					
	BW	Han et al., "Characterization of the DNF15S2 Locus on Human Chromosome 3: Identification of a Gene Coding for Four Kringle Domains with Homology to Hepatocyte Growth Factor" <u>Biochemistry</u> 30:9768-9780 (1991)					
	BX	Harris et al., "Therapeutic Antibodies - The Coming of Age" <u>TIBTECH</u> 11:42-44 (February 1993)					
	BY	Hartmann et al., "A Functional Domain in the Heavy Chain of Scatter Factor/Hepatocyte Growth Factor Binds the c-Met Receptor and Induces Cell Dissociation but Not Mitogenesis" <u>Proc. Natl. Acad. Sci. USA</u> 89:11574-11578 (December 1992)					
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	BZ	Hoogenboom and Winter, "By-passing immunisation: human antibodies from synthetic repertoires of germline V <sub>H</sub> gene segments rearranged in vitro" <u>J. Mol. Biol.</u> 227:381-388 (1992)	
	CA	Hunter et al., "Preparation of Iodine 131 Labelled Human Growth Hormone of High Specific Activity" <u>Nature</u> 194:495-496 (1962)	
	CB	Igawa et al., "Hepatocyte Growth Factor is a Potent Mitogen for Cultured Rabbit Renal Tubular Epithelial Cells" <u>Biochem. &amp; Biophys. Res. Comm.</u> 174(2):831-838 (January 31, 1991)	
	CC	Iyer et al., "Structure, Tissue-Specific Expression, and Transforming Activity of the Mouse met Protooncogene" <u>Cell Growth &amp; Differentiation</u> pps. 87-95 (1990)	
	CD	Jakobovits et al., "Analysis of Homozygous Mutant Chimeric Mice: Deletion of the Immunoglobulin Heavy-Chain Joining Region Blocks B-cell Development and Antibody Production" <u>Proc. Natl. Acad. Sci. USA</u> 90:2551-2555 (March 1993)	
	CE	Jakobovits et al., "Germ-line Transmission and Expression of a Human-Derived Yeast Artificial Chromosome" <u>Nature</u> 362:255-258 (March 18, 1993)	
	CF	Jones et al., "Replacing the Complementarity-determining Regions in a Human Antibody with Those From a Mouse" <u>Nature</u> 321:522-525 (May 29, 1986)	
	CG	Kabat et al., "Sequences of Proteins of Immunological Interest", Bethesda, MD:National Institute of Health (1983)	
	CH	Kohler et al., "Continuous Cultures of Fused Cells Secreting Antibody of Predefined Specificity", <u>Nature</u> 256:495-497 (August 7, 1975)	
	CI	Kozbor et al., "A Human Hybrid Myeloma for Production of Human Monoclonal Antibodies" <u>The Journal of Immunology</u> 133(6):3001-3005 (1984)	
	CJ	Lindroos et al., "Hepatocyte Growth Factor (Hepatopoietin A) Rapidly Increases in Plasma before DNA Synthesis and Liver Regeneration Stimulated by Partial Hepatectomy and Carbon Tetrachloride Administration" <u>Hepatology</u> 13(4):743-750 (1991)	
	CK	Lokker et al., "Generation and Characterization of a Competitive Antagonist of Human Hepatocyte Growth Factor, HGF/NK1", <u>Journal of Biological Chemistry</u> 268(23):17145-17150 (August 15, 1993)	
	CL	Lokker et al., "Structure-Function Analysis of Hepatocyte Growth Factor: Identification of Variants that Lack Mitogenic Activity Yet Retain High Affinity Receptor Binding" <u>EMBO Journal</u> 11(7):2503-2510 (1992)	
	CM	Mark et al., "Expression and Characterization of Hepatocyte Growth Factor Receptor-IgG fusion Proteins" <u>The Journal of Biological Chemistry</u> 267(36):26166-26171 (December 25, 1992)	
	CN	Marks et al., "By-passing immunization: human antibodies from V-gene libraries displayed on phage" <u>J. Mol. Biol.</u> 222:581-597 (1991)	
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	CO	Matsumoto et al., "Deletion of Kringle Domains or the N-Terminal Hairpin Structure in Hepatocyte Growth Factor Results in Marked Decreases in Related Biological Activities" <u>Biochem. &amp; Biophys. Res. Comm.</u> 181(2):691-699 (December 16, 1991)					
	CP	Matsumoto et al., "Hepatocyte Growth Factor is a Potent Stimulator of Human Melanocyte DNA Synthesis and Growth" <u>Biochem. &amp; Biophys. Res. Comm.</u> 176(1):45-51 (April 15, 1991)					
	CQ	Michalopoulos et al., "Control of Hepatocyte Replication by Two Serum Factors" <u>Cancer Research</u> 44:4414-4419 (October 1984)					
	CR	Miyazawa et al., "An Alternatively Processed mRNA Generated from Human Hepatocyte Growth Factor Gene" <u>European Journal of Biochemistry</u> 197:15-22 (1991)					
	CS	Miyazawa et al., "Molecular Cloning and Sequence Analysis of cDNA for Human Hepatocyte Growth Factor" <u>Biochem. &amp; Biophys. Res. Comm.</u> 163(2):967-973 (September 15, 1989)					
	CT	Montesano et al., "Identification of a Fibroblast-Derived Epithelial Morphogen as Hepatocyte Growth Factor" <u>Cell</u> 67:901-908 (November 29, 1991)					
	CU	Morrison et al., "Chimeric Human Antibody Molecules: Mouse Antigen-binding Domains with Human Constant Region Domains" <u>Proc. Natl. Acad. Sci. USA</u> 81:6851-6855 (November 1984)					
	CV	Munson et al., "LIGAND: A Versatile Computerized Approach for Characterization of Ligand-Binding Systems" <u>Analytical Biochemistry</u> 107:220-239 (1980)					
	CW	Naka et al., "Activation of Hepatocyte Growth Factor by Proteolytic Conversion of a Single Chain Form to a Heterodimer" <u>The Journal of Biological Chemistry</u> 267(28):20114-20119 (1992)					
	CX	Nakamura et al., "Molecular Cloning and Expression of Human Hepatocyte Growth Factor" <u>Nature</u> 342:440-443 (November 23, 1989)					
	CY	Nakamura et al., "Partial Purification and Characterization of Hepatocyte Growth Factor from Serum of Hepatectomized Rats" <u>Biochem. &amp; Biophys. Res. Comm.</u> 122:1450-1459 (August 16, 1984)					
	CZ	Nakamura et al., "Purification and Characterization of a Growth Factor from Rat Platelets for Mature Parenchymal Hepatocytes in Primary Cultures" <u>Proc. Natl. Acad. Sci. USA</u> 83:6489-6493 (1986)					
	DA	Nakamura et al., "Purification and Subunit Structure of Hepatocyte Growth Factor from Rat Platelets" <u>FEBS Letters</u> 224(2):311-316 (November 1987)					
	DB	Naldini et al., "Hepatocyte Growth Factor (HGF) Stimulates the Tyrosine Kinase Activity of the Receptor Encoded by the Proto-Oncogene c-MET" <u>Oncogene</u> 6:501-504 (1991)					
	DC	Naldini et al., "Scatter Factor and Hepatocyte Growth Factor are Indistinguishable Ligands for the MET Receptor" <u>EMBO Journal</u> 10(10):2867-2878 (1991)					
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	DD	Novotny and Haber, "Structural invariants of antigen binding: Comparison of immunoglobulin V <sub>L</sub> -V <sub>H</sub> and V <sub>L</sub> -V <sub>L</sub> domain dimers" <u>Proc. Natl. Acad. Sci. USA</u> 82(14):4592-4596 (July 1985)					
	DE	Nygren, H., "Conjugation of Horseradish Peroxidase to Fab Fragments with Different Homobifunctional and Heterobifunctional Cross-Linking Reagents" <u>The Journal of Histochemistry and Cytochemistry</u> 30(5):407-412 (1982)					
	DF	Okajima et al., "Primary Structure of Rat Hepatocyte Growth Factor and Induction of Its mRNA During Liver Regeneration Following Hepatic Injury" <u>European Journal of Biochemistry</u> 193:375-381 (1990)					
	DG	Pain et al., "Preparation of Protein A-Peroxidase Monoconjugate Using a Heterobifunctional Reagent, and its Use in Enzyme Immunoassays" <u>Journal of Immunological Methods</u> 40:219-230 (1981)					
	DH	Palacios et al., "IL3-Dependent Mouse Clones That Express B-220 Surface Antigen, Contain Ig Genes in Germ-Line Configuration, and Generate B Lymphocytes In Vivo" <u>Cell</u> 41:727-734 (1985)					
	DI	Park et al., "Sequence of MET Protooncogene cDNA has Features Characteristic of the Tyrosine Kinase Family of Growth-Factor Receptors" <u>Proc. Natl. Acad. Sci. USA</u> 84:6379-6383 (1987)					
	DJ	Ponzetto et al., "c-met is Amplified But Not Mutated in a Cell Line with an Activated met Tyrosine Kinase" <u>Oncogene</u> 6:553-559 (1991)					
	DK	Ponzetto et al., "A Novel Recognition Motif for Phosphatidylinositol 3-Kinase Binding Mediates Its Association With The Hepatocyte Growth Factor/Scatter Factor Receptor" <u>Molecular &amp; Cellular Biology</u> 13(8):4600-4608 (1993)					
	DL	Prat et al., "C-Terminal Truncated Forms of Met, the Hepatocyte Growth Factor Receptor" <u>Molecular &amp; Cellular Biology</u> 11(12):5954-5962 (1991)					
	DM	Prat et al., "The Receptor Encoded by the Human c-Met Oncogene is Expressed in Hepatocytes, Epithelial Cells and Solid Tumors" <u>Int. J. Cancer</u> 49:325-328 (1991)					
	DN	Prat, et al., "The HGF Receptor (Met): Transduction of Signals for Invasive Cell Growth" <u>Antibody, Immunoconjugates, and Radiopharmaceuticals</u> , Volume 8, Number 4, pps. 341-361 (1995)					
	DO	Presta et al., "Humanization of an Antibody Directed Against IgE" <u>J. Immunol.</u> 151(5):2623-2632 (September 1, 1993)					
	DP	Presta L., "Antibody Engineering" <u>Curr. Op. Struct. Biol.</u> 2:593-596 (1992)					
	DQ	Remington <u>Pharmaceutical Sciences</u> , Oslo et al. eds., 16 <sup>th</sup> edition, Mack Publishing (1980)					
	DR	Riechmann et al., "Reshaping Human Antibodies for Therapy" <u>Nature</u> 332:323-327 (march 24, 1988)					
	DS	Rodrigues et al., "Alternative Splicing Generates Isoforms of the met Receptor Tyrosine Kinase Which Undergo Differential Processing" <u>Molecular &amp; Cellular Biology</u> 11(6):2962-2970 (1991)					
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	DT	Rubin et al., "A Broad-Spectrum Human Lung Fibroblast-Derived Mitogen is a Variant of Hepatocyte Growth Factor" <u>Proc. Natl. Acad. Sci. USA</u> 88:415-419 (1991)					
	DU	Russell et al., "Partial Characterization of a Hepatocyte Growth Factor From Rat Platelets" <u>J. Cellular Physiology</u> 119:183-192 (1984)					
	DV	Seki et al., "Isolation and Expression of cDNA for Different Forms of Hepatocyte Growth Factor from Human Leukocyte" <u>Biochem. and Biophys. Res. Commun.</u> 172(1):321-327 (October 15, 1990)					
	DW	Sims et al., "A Humanized CD18 Antibody Can Block Function Without Cell Destruction" <u>The Journal of Immunology</u> 151(4):2296-2308 (Aug 1993)					
	DX	Smith et al., "Cardiac Glycoside-Specific Antibodies in the Treatment of Digitalis Intoxication" <u>Antibodies in Human Diagnosis and Therapy</u> pps. 365-389 (1977)					
	DY	Stoker et al., "Scatter Factor is a Fibroblast-Derived Modulator of Epithelial Cell Mobility" <u>Nature</u> 327:239-242 (May 21, 1987)					
	DZ	Sunitha et al., "Hepatocyte Growth Factor Stimulates Invasion Across Reconstituted Basement Membranes by a New Human Small Intestinal Cell Line" <u>Clin. Exp. Metastasis</u> 12:143-154 (1994)					
	EA	Tashiro et al., "Deduced Primary Structure of Rat Hepatocyte Growth Factor and Expression of the mRNA in Rat Tissues" <u>Proc. Natl. Acad. Sci. USA</u> 87:3200-3204 (1990)					
	EB	Upstate Biotechnology Inc. <u>Anti-human Met Monoclonal Antibodies</u> (product literature)					
	EC	Verhoeyen et al., "Reshaping Human Antibodies: Grafting an Antilysozyme Activity" <u>Science</u> 239:1534-1536					
	ED	Weidner et al., "Scatter Factor: Molecular Characteristics and Effect on the Invasiveness of Epithelial Cells" <u>Journal of Cell Biology</u> 111:2097-2108 (November 1990)					
	EE	Yamada et al., "Immunohistochemistry with Antibodies to Hepatocyte Growth Factor and its Receptor Protein (c-MET) in Human Brain Tissues" <u>Brain Research</u> 637:308-312 (1994)					
	EF	Zola, "Using Monoclonal Antibodies: Soluble Antigens" <u>Monoclonal Antibodies: A Manual of Techniques</u> , CRO Press, Chapter 6, pps. 147-158 (1987)					
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